must be given an emergency still process (developed per § 431.3(b)) before the retort is cooled or the retort must be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown must be removed and either reprocessed, repacked and reprocessed and or destroyed. Product to be destroyed must be handled as ''U.S. Inspected and Condemned,'' as defined in § 301.2 of this chapter, or as ''U.S. Condemned,'' as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(*2*) The time the retort reel stopped and the time the retort is used for an emergency still retort process must be noted on the temperature/time recording device and entered on the other production records required in § 431.7.

(B) *Temperature drops.* When the retort temperature drops below the temperature specified in the process schedule, the reel must be stopped and the following actions must be taken:

(*1*) For temperature drops of less than 10 °F (or 5.5 °C) either:

(*i*) All containers in the retort must be given an emergency still process (developed per § 431.3(b)) before the reel is restarted;

(*ii*) Container entry to the retort must be prevented and an emergency agitating process (developed per § 431.3(b)) must be used before container entry to the retort is restarted; or

(*iii*) Container entry to the retort must be prevented and the reel restarted to empty the retort. The discharged containers must be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed must be handled as ''U.S. Inspected and Condemned,'' as defined in § 301.2 of this chapter, or as ''U.S. Condemned,'' as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(*2*) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort must be given an emergency still process (developed per § 431.3(b)). The time the reel was stopped and the time the retort was used for a still retort process must be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 431.7. Alternatively, container entry to the retort must be prevented and the reel restarted to empty the retort. The discharged containers must be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed must be handled as ''U.S. Inspected and Condemned,'' as defined in § 301.2 of this chapter, or as ''U.S. Condemned,'' as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(2) *Deviations identified through record review.* Whenever a deviation is noted during review of the processing and production records required by § 431.8(a) and (b), the establishment must hold the product involved and the deviation must be handled in accordance with paragraphs (c)(1)(iii) and (iv) of this section.

(d) *Process deviation file.* The establishment must maintain full records regarding the handling of each deviation. Such records must include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records must be maintained in a separate file or in a log that contains the appropriate information. The file or log must be retained in accordance with § 431.8(e) and must be made available to Program employees upon request.

§ 431.10 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) An HACCP plan for canned product that addresses hazards associated with microbiological contamination;

(2) An FSIS-approved total quality control system;

(3) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(4) Paragraph (b) of this section.

(b) Procedures for handling finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Incubation of shelf stable canned product*—(i) *Incubator.* The establishment must provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature.* The incubation temperature must be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature must be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) must be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation.* Shelf stable product requiring incubation includes:

(A) Low acid products as defined in § 431.1; and

(B) Acidified low acid products as defined in § 431.1.

(iv) *Incubation samples.* (A) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment must select at least one container for incubation.

(B) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment must select at least one container per 1,000 for incubation.

(C) Only normal-appearing containers must be selected for incubation.

(v) *Incubation time.* Canned product requiring incubation must be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (b)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance.* Designated establishment employees must visually check all containers under incubation each working day and the inspector must be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment must record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment must retain such records, along with copies of the temperature/time recording charts, in accordance with § 431.8(d).

(vii) *Abnormal containers.* The finding of abnormal containers (as defined in § 431.1) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping.* No product must be shipped from the establishment before the end of the required incubation period. An establishment wishing to ship product prior to the completion of the required incubation period must submit a written proposal to the District Office. Such a proposal must include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the District Office, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) [Reserved]

(c) *Container condition*—(1) *Normal containers.* Only normal-appearing containers must be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to program employees.

(2) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment must inform the inspector, and the affected code lot(s) must not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

§ 431.11 Personnel and training.

All operators of thermal processing systems specified in § 431.6 and container closure technicians must be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

§ 431.12 Recall procedure.

Establishments must prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure must be made available to Program employees for review.

PART 439—ACCREDITATION OF NON-FEDERAL CHEMISTRY LABORATORIES

Sec.
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AUTHORITY: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 73 FR 52196, Sept. 9, 2008, unless otherwise noted.

§ 439.1 Definitions.

(a) *Accreditation*—Determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation specified in this part, for the presence and amount of all four food chemistry analytes (protein, moisture, fat, and salt); or a determination by FSIS that a laboratory is qualified to analyze official samples of raw or processed meat and poultry products, because it has met the requirements for accreditation in this part, for the presence and amount of a specified chemical residue of any one of several classes of chemical residues. A laboratory may hold more than one accreditation.

(b) *Accredited laboratory*—A non-Federal analytical laboratory that has met the requirements for accreditation specified in this Part and, therefore, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

(c) *Accredited Laboratory Program (ALP)*—The FSIS program in which non-Federal laboratories are accredited as eligible to perform analyses on official regulatory samples of raw or processed meat and poultry products, and through which a check sample program for quality assurance is conducted.

(d) *Chemical residue misidentification*—see ''Correct chemical residue identification'' definition.

(e) *Coefficient of variation (CV)*—The standard deviation of a distribution of analytical values multiplied by 100 and divided by the mean of those values.

(f) *Comparison mean*—The average result, for a sample, obtained from all submitted results that have a large deviation measure of zero. When only two laboratories perform the analysis and the large deviation measure is not zero, alternative procedures for establishing a comparison mean may be employed by FSIS. For purposes of computing the comparison mean, a laboratory's ''result'' for a food chemistry analyte is the obtained analytical value; a laboratory's ''result'' for a chemical residue is the logarithmic transformation of the obtained analytical value.

(g) *Correct chemical residue identification*—Reporting by a laboratory of the presence and analytical value of a chemical residue that was included in